

**Region 4
U.S. Environmental Protection Agency
Science and Ecosystem Support Division
Athens, Georgia**

OPERATING PROCEDURE

Title: Internal Audits

Effective Date: October 23, 2014

Number: SESDPROC-008-R3

Authors

Name: Bobby Lewis

Title: Life Scientist

Signature: 

Date: 10/21/14

Approvals

Name: John Deatruck


Title: Chief, Enforcement and Investigations Branch

Signature: 

Date: 10/22/14

Name: Laura Ackerman

Title: Acting Chief, Ecological Assessment Branch

Signature: 

Date: 10/21/14

Name: Hunter Johnson

Title: Field Quality Manager, Science and Ecosystem Support Division

Signature: 

Date: 10/21/14

Revision History

The top row of this table shows the most recent changes to this controlled document. For previous revision history information, archived versions of this document are maintained by the SESD Document Control Coordinator on the SESD local area network (LAN).

History	Effective Date
<p>SESDPROC-008-R3, <i>Internal Audits</i>, Replaces SESDPROC-008-R2</p> <p>General: Corrected any typographical, grammatical, and/or editorial errors. Throughout the document mention of quality system or SESD quality system was replaced with Field Branches Quality System or FBQS.</p> <p>Cover Page: Changed the Author from Liza Montalvo to Bobby Lewis. Changed the Enforcement and Investigations Branch Chief from Archie Lee to John Deatrick. Changed the Ecological Assessment Branch Chief from Bill Cosgrove to Acting Chief, Laura Ackerman. Changed the FQM from Liza Montalvo to Bobby Lewis.</p> <p>Revision History: Changes were made to reflect the current practice of only including the most recent changes in the revision history.</p> <p>Section 1.2: Added the following statement – “Mention of trade names or commercial products in this operating procedure does not constitute endorsement or recommendation for use.”</p>	October 23, 2014
SESDPROC-008-R2, <i>Internal Audits</i> , Replaces SESDPROC-008-R1	September 8, 2010
SESDPROC-008-R1, <i>Internal Audits of the Quality System</i> , Replaces SESDPROC-008-R0	October 19, 2007
SESDPROC-008-R0, <i>Internal Audits of the Quality System</i> , Original Issue	February 5, 2007

TABLE OF CONTENTS

1	General Information	4
1.1	Purpose.....	4
1.2	Scope/Application	4
1.3	Documentation/Verification.....	4
1.4	Definitions.....	4
1.4.1	<i>Audit</i>	4
1.4.2	<i>Audit Criteria</i>	4
1.4.3	<i>Audit Evidence</i>	4
1.4.4	<i>Auditee</i>	4
1.4.5	<i>Auditor</i>	4
1.4.6	<i>Audit Team</i>	5
1.4.7	<i>Concern</i>	5
1.4.8	<i>Nonconformance</i>	5
1.5	References	5
2	Methodology	6
2.1	Summary of Procedure.....	6
2.2	Audit Schedule	6
2.3	Audit Tracking.....	6
2.4	Audit Plan	7
2.5	Audit Team	7
2.6	Conducting an Audit.....	7
2.7	Corrective Action	8
2.8	Preventive Action	8
2.9	Internal Auditor Training.....	8
2.10	Records.....	9

1 General Information

1.1 Purpose

This document defines the procedures used to conduct internal audits of the SESD Field Branches Quality System (FBQS) and technical operations in order to identify areas requiring corrective action, areas that would benefit from quality improvements and commendable practices.

1.2 Scope/Application

This procedure applies to SESD personnel who conduct work within or conduct audits of the SESD Field Branches Quality System. Mention of trade names or commercial products in this operating procedure does not constitute endorsement or recommendation for use.

1.3 Documentation/Verification

This procedure was prepared by persons deemed technically competent by SESD management, based on their knowledge, skills and abilities. The official copy of this procedure resides on the SESD Local Area Network (LAN). The Document Control Coordinator (DCC) is responsible for ensuring the most recent version of the procedure is placed on the LAN and for maintaining records of review conducted prior to its issuance.

1.4 Definitions

1.4.1 Audit

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

1.4.2 Audit Criteria

Set of policies, procedures or requirements.

1.4.3 Audit Evidence

Records, statements of fact or other information, which are relevant to the audit criteria and verifiable

1.4.4 Auditee

Organization or individuals being audited.

1.4.5 Auditor

Person with the competence to conduct an audit.

1.4.6 Audit Team

One or more auditors conducting an audit.

1.4.7 Concern

Practices thought to have potential detrimental effect on the Field Branches operational effectiveness or the quality of sampling, measurement or calibration results

1.4.8 Nonconformance

Departure from or absence of a specified requirement.

1.5 References

Audit Schedule, SESDFORM-032, Most Recent Version

Internal Audit Checklist, SESDFORM-040, Most Recent Version

Internal Audit Report, SESDFORM-041, Most Recent Version

ISO 19011: 2002(E), Guidelines for quality and/or environmental management systems auditing

SESD On-the-Job Training Form, SESDFORM-002, Most Recent Version

SESD Operating Procedure for Corrective Action, SESDPROC-009, Most Recent Version

SESD Operating Procedure for Preventive Action and Quality Improvement, SESDPROC-017, Most Recent Version

USEPA Region 4 Environmental Investigations Standard Operating Procedures and Quality Assurance Manual (EISOPQAM), November 2001

2 Methodology

2.1 Summary of Procedure

The goal of the internal auditing program is to provide a means of evaluating the adequacy, implementation and effectiveness of the SESD FBQS. The adequacy of the FBQS is evaluated by determining if the applicable policies, procedures, guidance documents, practices, facilities, equipment and materials are adequate for the task. The implementation of the FBQS is evaluated to determine if the applicable policies, procedures and guidance documents are implemented as intended. The effectiveness of the FBQS is evaluated to determine if the applicable policies, procedures and guidance documents are achieving intended results.

This procedure discusses how internal audits will be conducted in order to determine if quality management and technical operations within the field branches are in compliance with requirements of the SESD FBQS. Internal audits will be scheduled annually by the FQM. An internal audit that has not been scheduled can be requested by management, quality staff, internal auditors or external auditors. Internal audits will be conducted by trained staff who are, whenever possible, independent of the activity to be audited. Each audit can produce findings of nonconformances requiring quality improvements and/or corrective action as well as commendable practices. In the event that audit findings cast doubt on the correctness and/or validity of reported results, the FQM will initiate a corrective action to address those audit findings, including notifying the customer whose work has been affected in a timely manner.

2.2 Audit Schedule

In December of each year, the FQM will develop and maintain an audit schedule for the upcoming year. The schedule will address both internal and external audits. The focus of internal audits will be the components of the FBQS and technical operations, previous audit findings and corrective action requests. All components will be audited each year. Additional audits may be scheduled based on requests and/or recommendations from management and the Branch Quality Assurance Officers. The FQM will update the audit schedule if audits are added.

2.3 Audit Tracking

Audits will be uniquely identified to facilitate tracking. Audit tracking numbers will begin with IA for Internal Audits and EA for external audits, followed by a seven digit number. The first four digits will represent the calendar year. The last three digits will begin at 001 and increase sequentially with each additional audit. The last three digits will start over at 001 at the beginning of each calendar year (Ex. IA2007-001). The FQM will track audits using the Audit Schedule (SESDFORM-032).

2.4 Audit Plan

The FQM will prepare an audit plan that will describe:

1. the audit objectives;
2. the audit criteria;
3. the audit scope;
4. the dates and place where the audit activities will be conducted;
5. the expected time and duration of the audit; and
6. the roles and responsibilities of the audit team members.

The FQM will define the audit objectives, scope and criteria. The audit objectives define what is to be accomplished by the audit. The audit scope describes the extent and boundaries of the audit such as the activities and processes to be audited. The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedure, standards and management system requirements.

The FQM will discuss the audit plan with the affected management for approval.

2.5 Audit Team

The FQM in consultation with management will assemble an audit team and designate an audit team leader. The audit team may be sub-divided into several smaller teams depending on the scope of the audit. A team can consist of one or more individuals as needed. The audit team leader(s) will be responsible for facilitating the audit and preparing the audit report for his/her team.

2.6 Conducting an Audit

Internal audits will include interviews, examination of documents and records, and observation of pertinent facilities, equipment, and activities. Audits will be scheduled and announced in advance of the actual audit. The audit team(s) will be responsible for preparing a checklist in order to facilitate complete coverage of the important aspects of the area/process being audited. The audit checklist will address:

1. The subject to be evaluated.
2. The document(s)/activity upon which the audit is based.
3. The questions asked and responses received.
4. The information provided by the personnel that were audited

After the audit is conducted, the team(s) will brief the auditees, the FQM and affected management regarding the results. This discussion will include nonconformances, concerns and commendable practices. This meeting provides an opportunity for reviewing, clarifying and verifying information gathered during the audit. A written

report will be prepared by the audit team leader(s) within 30 days of completion of the audit. The report will identify the area or activity audited, any nonconformances or concerns with specific reference to the document(s) used as the basis for conducting the audit (e.g. accreditation standard, quality management plan, policy, procedure, guidance document, training manual) and commendable findings.

The report(s) will be transmitted to the FQM. The FQM will evaluate the report(s) to determine if there is a need for a corrective action, preventive action or quality improvement. The FQM will prepare a final report along with any actions to be taken and will distribute to management and the Branch QAOs. Nonconformances will be remediated via the Field Branches corrective action process as described in Section 2.7 below. Concerns will be evaluated by the FQM and handled as described in Section 2.8 below.

2.7 Corrective Action

Corrective actions resulting from an audit will be handled in accordance with the SESD Operating Procedure for Corrective Action (SESDPROC-009). The FQM will monitor progress of the corrective actions and conduct follow-up audits as necessary to ensure the issue has been resolved.

2.8 Preventive Action

Any area of concern, not meeting the definition of a nonconformance, which results from an audit, should be reviewed as a candidate for preventive action or quality improvement to be undertaken by SESD management. Preventive actions and quality improvements will be handled in accordance with the SESD Operating Procedure for Preventive Actions and Quality Improvements (SESDPROC-017).

2.9 Internal Auditor Training

Audits will be conducted by the FQM and other trained auditors. The FQM and management are responsible for identifying training opportunities for SESD Internal Auditors. The training will address the basics needed to plan, conduct, record and report audits of the SESD FBQS and technical operations and their associated documentation. The FQM will keep a record for each auditor showing training and experience accumulated by conducting internal audits. Auditor training can also be provided by trained auditors during SESD internal audits and a record of the training will be documented in the SESD On-the-Job Training Form SESDFORM-002.

In order to maintain status as an internal auditor, an individual must participate in at least one internal audit within two years or attend auditor training.

2.10 Records

Records associated with the implementation of this procedure will be maintained by the FQM. These records include but are not limited to:

1. Audit Schedule
2. Audit Plans
3. Audit Checklists
4. Audit Reports
5. Corrective Action Records
6. Preventive Action Records
7. Quality Improvement Records
8. Auditor Training Records.